§ 58.205

SUPPLEMENTAL SPECIFICATIONS FOR PLANTS MANUFACTURING, PROCESSING, AND PACKAGING NONFAT DRY MILK, INSTANT NONFAT DRY MILK, DRY WHOLE MILK, AND DRY BUTTERMILK

DEFINITIONS

§ 58.205 Meaning of words.

For the purpose of the regulations in this subpart, words in the singular form shall be deemed to impart the plural and vice versa, as the case may demand. Unless the context otherwise requires, the following terms shall have the following meaning:

- (a) Nonfat dry milk. The product obtained by the removal of only water from pasteurized skim milk. It contains not more than 5 percent by weight of moisture and not more than 1½ percent by weight of milkfat and it conforms to the applicable provisions of 21 CFR 131 "Milk and Cream" as issued by the Food and Drug Administration. Nonfat dry milk shall not contain nor be derived from dry buttermilk, dry whey, or products other than skim milk, and shall not contain any added preservative, neutralizing agent, or other chemical.
- (b) Instant nonfat dry milk. Instant nonfat dry milk is nonfat dry milk which has been produced in such a manner as to substantially improve its dispersing and reconstitution characteristics over that produced by the conventional process. Instant nonfat dry milk shall not contain dry buttermilk, dry whey, or products other than nonfat dry milk, except that lactose may be added as a processing aid during instantizing. The instant nonfat dry milk shall not contain any added preservatives, neutralizing agent, or other chemical. If lactose is used, the amount of lactose shall be the minimum required to produce the desired effect, but in no case shall the amount exceed 2.0 percent of the weight of the nonfat dry milk. If instant nonfat dry milk is fortified with vitamin A, and the product is reconstituted in accordance with the label directions, each quart of the reconstituted product shall contain 2000 International Units thereof. If instant nonfat dry milk is fortified with vitamin D, and the product is reconstituted in accordance with

the label directions, each quart of the reconstituted product shall contain 400 International Units thereof.

- (c) Dry whole milk. The pasteurized product resulting from the removal of water from milk and contains the lactose, milk proteins, milk fat, and milk minerals in the same relative proportions as in the fresh milk from which made. The milk may be standardized but shall not contain buttermilk, or any added preservative, neutralizing agent or other chemicals.
- (d) Dry buttermilk. The product resulting from drying liquid buttermilk that was derived from the churning of butter and pasteurized prior to condensing at a temperature of 161 °F for 15 seconds or its equivalent in bacterial destruction. Dry buttermilk shall have a protein content of not less than 30.0 percent. Dry buttermilk shall not contain nor be derived from nonfat dry milk, dry whey, or products other than buttermilk, and shall not contain any added preservative, neutralizing agent, or other chemical.
- (e) Dry buttermilk product. The product resulting from drying liquid buttermilk that was derived from the churning of butter and pasteurized prior to condensing at a temperature of 161 °F for 15 seconds or its equivalent in bacterial destruction. Dry buttermilk product has a protein content less than 30.0 percent. Dry buttermilk product shall not contain nor be derived from nonfat dry milk, dry whey, or products other than buttermilk, and shall not contain any added preservative, neutralizing agent, or other chemical.

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ROOMS AND COMPARTMENTS

§ 58.210 Dry storage of product.

Storage rooms for the dry storage of product shall be adequate in size, kept clean, orderly, free from rodents, insects, and mold, and maintained in good repair. They shall be adequately lighted and ventilated. The ceilings, walls, beams and floors should be free

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from structural defects and inaccessible false areas which may harbor insects

§ 58.211 Packaging room for bulk products.

A separate room or area shall be provided for filling bulk containers, and shall be constructed in accordance with §58.126. The number of control panels and switch boxes in this area should be kept to a minimum. Control panels shall be mounted a sufficient distance from the walls to facilitate cleaning or satisfactorily sealed to the wall, or shall be mounted in the wall and provided with tight fitting removable doors to facilitate cleaning. An adequate exhaust system shall be provided to minimize the accumulation of product dust within the packaging room and where needed, a dust collector shall be provided and properly maintained to keep roofs and outside areas free of dry product. Only packaging materials that are used within a day's operation may be kept in the packaging area. These materials shall be kept on metal racks or tables at least six inches off the floor. Unnecessary fixtures, equipment, or false areas which may collect dust and harbor insects, should not be allowed in the packaging room.

§58.212 Hopper or dump room.

A separate room shall be provided for the transfer of bulk dry dairy products to the hoppers and conveyors which lead to the fillers. This room shall meet the same requirements for construction and facilities as the bulk packaging operation. Areas and facilities provided for the transfer of dry dairy products from portable bulk bins will be accepted if gasketed surfaces or direct connections are used that appreciably eliminate the escape of product into the area.

§58.213 Repackaging room.

A separate room shall be provided for the filling of small packages and shall meet the same requirements for construction and facilities as the bulk packaging operation. EQUIPMENT AND UTENSILS

§58.214 General construction, repair and installation.

All equipment and utensils necessary to the manufacture of dry milk products, including pasteurizer, timingpump or device, flow diversion valve and recorder controller, shall meet the same general requirements as outlined in §58.128 of this subpart. In addition, for certain other equipment the following requirements shall be met.

§58.215 Pre-heaters.

The pre-heaters shall be of stainless steel or other equally corrosion resistant material, cleanable, accessible for inspection and shall be equipped with suitable automatic temperature controls.

§ 58.216 Hotwells.

The hotwells shall be enclosed or covered and should be equipped with indicating thermometers either in the hotwell or in the hot milk inlet line to the hotwell. If used for holding high heat products, they should also have recorders.

§ 58.217 Evaporators and/or vacuum pans.

Evaporators or vacuum pans or both, with open type condensers shall be equipped with an automatic condenser water level control, barometric leg, or so constructed so as to prevent water from entering the product. New or replacement units shall comply with the 3-A Sanitary Standards for Milk and Milk Products Evaporators and Vacuum Pans. When enclosed type condensers are used, no special controls are needed to prevent water from entering the product. Water collected from the condensing of product (cow water) in this equipment may be utilized for prerinsing and cleaning solution make-up; provided it is equipped with proper controls that will automatically divert water with entrained solids to the waste water system. "Cow water" shall not be used for acidified or final equipment rinse.

§ 58.218 Surge tanks.

If surge tanks are used for hot milk, and temperatures of product including